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Title:

Do levels of evidence affect breadth of service? A study on the use of clinical guidance in a learning disability service.

Eleni Pateraki^{1,2} and Kenneth Macmahon^{1,2}

¹Department of Clinical and Health Psychology, School of Health in Social Science, the University of Edinburgh, Medical School, Edinburgh, UK

²Adult Learning Disability Service, Clinical Psychology Department, Kirklands Hospital, Lanarkshire, UK

Correspondence

E. Pateraki, Adult Learning Disability Service, Clinical Psychology Department, Kirklands Hospital, Lanarkshire, UK, G71 8BB.

Email: eleni.pateraki@nhs.net

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Accessible summary

- The government suggests to the NHS what talking psychological therapies should be given to people when they have worries or problems.
- This study examined a service for people with learning disabilities in Scotland. It tried to find out whether the service was doing what the government suggests.
- The study found that the people who were seen by the service often had more than one difficulty, and the service gave extra talking psychological therapy to them.
- We think that this study shows that people with learning disabilities should have more treatments available for them to meet their needs.

Abstract

Background: For services across the UK, increasing emphasis is placed on the use of evidence-based psychological treatments. In this context, the Scottish Government published the MATRIX, a best-practice clinical governance document, with a brief section on therapies for people with learning disabilities. As with most clinical guidelines, randomised-controlled trials were considered the 'gold standard'. However, within the learning disability field the existing evidence-base is relatively limited, resulting in a narrow guidance for services.

Methods: This study evaluated the use of best-practice guidance (the MATRIX), in a Psychology service for adults with learning disabilities, covering one of the largest NHS Boards in Scotland. A randomly selected 50% ($N=73$) of case notes opened since October 2011 (publication date for the MATRIX) was reviewed. Eight case notes were second-rated by an independent clinician.

Results: Findings showed that service users typically presented with multiple psychological difficulties and clinicians offered a range of therapies additional to those suggested in the guidance. This was particularly evident in cases managed by Clinical Psychologists.

Conclusions: Applying rigid therapeutic recommendations may limit opportunities for integrative practice. The potential impact of inflexibly adopting clinical guidelines on service planning and resources is discussed.

Keywords: learning disabilities, psychological therapy, health & social care policy and practice, IAPT, MATRIX

Introduction

Mental health services across the UK, increasing emphasis continues to be placed upon the use of evidence-based interventions to help achieve government priorities regarding access to psychological therapies. Several guidelines now exist that summarise the most up-to-date empirically validated interventions for common mental health difficulties (e.g., NICE, 2009; 2015; SIGN, 2013).

As part of this drive to increase the availability and quality of mental health care, the Scottish Government and NHS Education Scotland (NES) produced the MATRIX (2008). This initiative aimed to provide health boards with guidance on strategic planning for mental health services. It offered a summary of empirically supported psychological therapies for specific psychological difficulties, such as depression or anger, to aid clinicians and managers to focus on the timely delivery of effective interventions to service users (Scottish Government, 2008). In clinical practice, the implementation of high quality guidance is associated with improved patient outcomes and reduced costs for healthcare organisations (Edejer, 2006; Holon et al., 2014).

The MATRIX was considered to be a positive development as it also validated the use of psychological therapies within the NHS. However, this initiative has given rise to a number of issues (e.g., Campbell, Robertson and Jahoda, 2014). Perhaps the primary concern is that such clinical guidance may govern the delivery of psychological services and the streaming of training and resources (Francke, Smit, de Veer and Mistiaen, 2008); yet it is based on a single diagnosis model. This may be neglecting the scientific process inherent in developing and testing hypotheses and

formulations with each service user. In services working with individuals with multiple morbidities, a formulation-based individualised approach tends to be favoured, in relation to standardised treatment protocols, to meet users' needs and improve outcomes (Zarbo, Tasca, Cattafi and Compare, 2016; Kinderman, Sellwood and Tai, 2008). Therefore, as the majority of service users are referred to mental health services without a formal diagnosis (Maitland et al., 2006) and often with multiple difficulties, adherence to guidance merely based on trial protocols may be challenging (Aylett, 2010). Indeed, several audits now suggest that implementation of clinical guidelines is often low, especially where local factors and increased complexity are not accounted for (Baird and Lawrence, 2014; Bauer, 2002; Jankowski, 2001).

These concerns regarding clinical guidelines are applicable to the general population who access mental health services. For individuals with learning disabilities, these effects may be magnified. Psychological therapies indicated for individuals without learning disabilities may not be as effective or suitable for individuals with learning disability (Bhaumik, Gangadharan, Hiremath and Russell, 2011; Beail and Jahoda, 2012). In addition, intervention trials referred in such clinical guidelines frequently exclude people with learning disability from their sample, thus making it difficult to provide substantive evidence for their use with this population. For example, although the use of cognitive-behavioural therapy is now seen as an effective intervention for many people with mild to moderate learning disability (Vereenooghe and Langdon, 2013), limited evidence exists for its use with individuals with more severe learning disability (Bhaumik et al., 2011). Additionally, there is a

paucity of studies on the use of other therapies, such interpersonal or systemic psychotherapy with people with learning disability (Beail and Jahoda , 2012).

In response, health departments across the UK published further guidance to ensure appropriate access to psychological treatments for everyone, with specialist support if required (e.g., the Positive Practice Guide for IAPT services; Department of Health, 2009). In Scotland, an extension of the MATRIX focusing on individuals with learning disability was included in its updated version (NES, 2011; 2015).

This development led to some additional difficulties. Research on this population is still in its infancy and it only represents a minor proportion of the research literature regarding the effectiveness of psychological therapies (Taylor, Lindsay and Willner, 2008). The MATRIX considered randomised controlled trials to be the 'gold' standard of evidence, thus many studies on this population did not meet the quality criteria for inclusion. This was mainly due to limited numbers of participants, absence of matched control groups and limited follow-up evaluations (Campbell et al., 2014). The slow progress of research in this field is often linked to the heterogeneity of people with learning disability posing challenges to recruitment, the need for increased flexibility in the delivery of psychological work limiting the potential of applying standardised approaches and ethical issues concerning capacity (Beail, 2010; Oliver et al., 2002).

Consequently, the above difficulties led to a very limited MATRIX for people with learning disability. Therapies for only five diagnoses met the appropriate empirical standards (anxiety, depression, psychosis, anger and challenging behaviour) and conclusions around effectiveness were based on a very small range of studies (NES,

2011; 2015). Indicative is the recommendation for anxiety, where behavioural relaxation training is the only recommended treatment in the guidance (NES, 2011; 2015). Thus, the dissonance between clinical reality and the guidance is accentuated. The MATRIX in its latest form may not reflect the broad range of therapies used in psychological services for people with learning disability. For instance, there is limited acknowledgement of the indirect work and training carried out with care providers, families, professionals and wider systems (Beail and Jahoda, 2012).

In line with other treatment guidelines, the MATRIX adopted strict criteria for research evidence, omitting observational and single case designs, or lower levels of evidence when higher quality research, such as randomised controlled trials or meta-analyses, existed in a given area (Campbell et al., 2014). The implications of using treatment guidelines, which adopt such rigid standards for acceptable evidence, have been extensively discussed in the literature. Criticisms emphasise the limited clinical relevance of recommendations that are based on artificial experimental conditions resulting in low external validity (Hatt, 2015; Shelton, 2014). Indeed, pilot studies or case reports may provide valid learning outcomes and useful insights into the secondary factors that contribute to therapeutic change; e.g., treatment engagement and motivation, therapeutic relationship and creative communication methods.

Present study

As the emphasis on efficacy and evidence-based therapies increases, in line with government priorities and policies across the UK (Department of Health, 2009; Scottish Government, 2012), there is a risk that only interventions included in best-

practice guidelines will be considered acceptable. Thus, the majority of training and resources will be focused upon these. The provision of psychological services will also be structured and evaluated around these (Francke et al., 2008). This, in turn, is likely to have several implications. For example, interventions that are currently used, and are considered effective within an integrative framework or by expert opinion (in the context of lack of other evidence) may no longer be offered (e.g., indirect work with carers). In addition, formulation skills, extensively utilised by psychologists, could become less valued in favour of standardised treatment protocols and clinicians could be invited to apply in their day-to-day practice manualised therapies devised through tightly controlled studies with samples that do not reflect the clinical population (e.g., without comorbidity) (Shelton, 2014). Consequently, service users with more complex presentations may not be adequately or appropriately treated.

Within this framework, there is a need to evaluate the implications of rigidly adopting such a methodology in the delivery of psychological services for individuals with learning disability, to ensure that service users continue to receive interventions that best meet their needs.

Aims

The present study aimed to investigate the possible effects of a rigid adoption of the MATRIX approach to a Psychology service for adults with learning disability. In line with the previously outlined concerns about the guidance, the following questions were addressed:

1. *What proportion of service users has an existing diagnosed disorder?*
2. *What proportion of service users presents with a referring problem for which there is a psychological intervention recommended in the MATRIX? and, what proportion of service users has more than one referring problems?*
3. *What proportion of psychological therapies provided in the service is recommended in the learning disabilities section of the MATRIX?*

The outcomes would allow an exploration of the potential applicability of a brief diagnostically-based clinical guidance and whether clinicians would be able to adopt the existing guidance for the range of the referring problems they actually receive within a service.

Methods

Overview

The case note review took place in a psychological service for adults with learning disability, covering one of the largest NHS Boards in Scotland. A random selection of 50% ($N = 73$) of all patient files opened between 1st October 2011 and 31st July 2013 were reviewed. October 2011 was chosen because this was the publication date of the updated version of the MATRIX, which included a section on psychological therapies for people with learning disability (NES, 2011). In 2015, a further update of the MATRIX was published (NES, 2015). The guidance, however, for individuals with learning disabilities remained unchanged.

The service, which is the single available team of psychological therapists for individuals with learning disabilities providing input to the entire NHS board,

comprised of five qualified clinical psychologists, three trainee clinical psychologists, a cognitive-behavioural therapist and a psychological therapist with expertise in behavior that challenges. All clinicians worked exclusively with clients with learning disabilities in the service.

Ethical Approval

Approvals by the local NHS Research and Development department and the Caldicott Guardian were obtained. The project was registered on the local NHS board Clinical Quality Register.

Procedure

The electronic patient allocation database was used to identify initial information for all referrals to the service within the audited time period. Out of the 184 patient referrals, one case note was missing and 37 cases were excluded due to referrals relating to neuropsychological assessments or diagnosis of learning disability. Although it is likely that these would still entail some level of psychological intervention (e.g., pre-diagnostic counseling, sign-posting, psycho-education, consultation), the initial reason for referral was not for therapeutic intervention. A limit of eight weeks prior to the start of data collection was set to ensure that some reporting of psychological assessment and intervention plan would have taken place, in keeping with the local care standards. Each of the remaining files was assigned an order number based on the date of referral. A random number generator (using random.org) was used to generate the random selection of 50% ($N = 73$) of the case files.

The data were collected using a purposefully designed form. In line with the aims of the study, data gathered included primary and secondary ICD-10 diagnosis, referring problem(s) and psychological intervention(s). The form outlined the diagnoses and psychological therapies included in the MATRIX in order to allow the rater to compare the work in each case note against these. It also provided a list of psychological therapies as a guide to support the raters. This list was compiled by the merging of the psychological therapies outlined in the UK Council for Psychotherapy (2013) and the treatments and definitions used by the Information Services Division. Data were sourced from the clinical correspondence in each case note, including referral letters, assessment or discharge reports. When data obtained from clinical correspondence were insufficient, other sources of information in the file, such as progress notes, were used.

A proportion of the reviewed case notes were second-rated by another clinician in the service, who was not involved in the development of this project. The second rater reviewed eight files (10.9%), which were randomly selected using the same method (random.org). A discussion between the raters followed to ensure that differences in the recording of the data were not due to systematic and consistent errors; e.g. definitions of mental health difficulties or psychological therapies.

Analysis

Descriptive statistics were produced to review the data with SPSS (19.0). The initial raw data regarding referrals and interventions were collapsed and grouped into wider categories to ensure consistency in the reporting.

Results

1. What proportion of service users has an existing diagnosed disorder?

Data regarding the presence of a formal ICD-10 diagnosis were mainly available from Psychiatry reports and correspondence. Learning disability was not included in the analysis of the percentages of formal diagnoses amongst files, as it was assumed to be present for all cases (due to the substantive screening process at initial referral to the service).

68.5% of the total cases had no formal diagnosis reported, 31.5% had at least one and 15.1% had more than one diagnoses. In relation to the diagnoses included in the MATRIX, 36.6% were referring to anxiety and depressive disorders and 9.8% to impairment of behaviour. 53.6% of reported diagnoses were not included the clinical governance document, for example pervasive developmental disorders and Down's syndrome (29.2%), hyperkinetic and sleep disorders (12.2%).

2. What proportion of service users presents with a referring problem for which there is a psychological intervention identified in the MATRIX? What proportion has more than one referring problems?

39.1% of the cases had one referring problem, 42.5% of the cases had two, and 17.8% had three or more referring problems. 90.4% of the cases had at least one referring problem included in the learning disabilities section of the MATRIX. More specifically, 67.1% ($N = 49$) of these cases had a referring problem that is one of the five included in the learning disabilities section of the MATRIX, and 23.3% ($N = 17$) had more than one such referring problem. Figure 1 presents an outline of the

referring problems identified across cases.

--- Figure 1 ---

3. What proportion of psychological therapies provided in the service is recommended in the learning disabilities section of the MATRIX?

An analysis of the psychological therapies offered across case notes is shown in Table 1. For four case files no intervention was provided and for three the service user disengaged prior to any psychological input; thus, these files ($n = 7$) were not included in the analysis of the range of psychological therapies offered in the service.

--- Table 1 ---

A mean of 2.55 interventions were identified for each case ($SD = 1.4$, range: 1-6). 36.4% of the cases ($n = 24$) received one intervention, 13.6% ($n = 9$) received two, 19.7% ($n = 13$) received three, 30.3% ($n = 20$) received four to six psychological interventions.

With regard to examining whether MATRIX therapies are sufficient for the assessed needs of service users, it was found that 47% of service users ($n = 31$) were not offered any of the interventions suggested in the MATRIX for their referred problem, 39.4% ($n = 26$) were offered one MATRIX-suggested intervention and 13.6% ($n = 9$) were offered two or more.

The majority of the total cases, even if they were offered a MATRIX-approved therapy also required an additional intervention (81.8%). Only 18.2% of the total cases ($n = 12$) were found to have been offered only MATRIX-approved interventions

(Figure 2). 28.8% ($n = 19$) used one additional intervention and 53% ($n = 35$) used three or more interventions that were not suggested by the MATRIX (Figure 2).

--- Figure 2 ---

Interventions that were suggested within the MATRIX (e.g., social problem-solving for challenging behaviour), but were provided in response to a referring problem other than that defined in the MATRIX (e.g., anxiety or depression), were not considered to be MATRIX-recommended treatments. Furthermore, relaxation treatments in the context of anxiety were not marked as MATRIX-recommended interventions unless they involved behavioural relaxation training techniques¹.

Interestingly, 57.1% ($n = 28$) of service users that worked with a Clinical Psychologist or a trainee Clinical Psychologist were not offered any psychological therapy included in the MATRIX. However, only 17.6% ($n = 3$) of cases managed by Specialist Psychological Therapists (i.e., Challenging behaviour or CBT Practitioners) used therapies outwith the MATRIX.

With regard to the relationship between diagnosis and psychological intervention provided, in 25.4% of the cases ($n = 16$), excluding those with unspecified or no input, the intervention did not match the diagnosis. In 60.4% ($n = 38$) this was not possible to examine as the cases did not have a formal diagnosis. In contrast, in 82.5% of the cases ($n = 52$) an intervention was offered to address the referring problem.

Inter-rater reliability

The analysis of the inter-rater reliability was performed using the Cohen's kappa statistic. The level of agreement between raters was established for (i) presence of formal diagnosis (Kappa = 0.79, $p < 0.001$), (ii) referring problem (Kappa = 0.68, $p < 0.001$), and (iii) interventions provided (Kappa = 0.64, $p < 0.001$). Landis and Koch (1977) suggest that values of Kappa over 0.61 show a substantial level of agreement, although most statisticians prefer values higher than 0.71 (Landis and Koch, 1977).

Discussion

Increasing emphasis continues to be placed on the timely and skilled delivery of evidence-based psychological treatments, in line with government priorities and policies (Department of Health, 2009; Scottish Government, 2012). As part of this drive, the focus of resources is likely to be invested in training and practice approved by best-practice guidelines that emphasise the use of empirically validated interventions for specific diagnoses or problem areas, such as the MATRIX (NES, 2011). The present study explored the use of such guidance in a Psychology service for adults with learning disabilities and its potential implications if adopted rigidly.

Consistent with findings by Maitland and colleagues (2006), results showed that the majority (68.5%) of the cases were referred to the service without a formal ICD-10 diagnosis; thus, creating the need for clinicians to identify a diagnostic category in order to follow the relevant therapy, if working within the diagnostic structure of best-practice guidelines, such as the MATRIX. In addition, of the cases where diagnosis was available, less than half (48.8%) matched one of the five included in the MATRIX to allow the direct implementation of the guidance. In contrast, 90.4% of the cases were found to have at least one identified referring problem that

matched one of the five areas included in the guidance.

A relatively low proportion of cases (18.2%) were found to have solely been offered interventions suggested in the MATRIX. As expected, a large percentage of service users were offered a mix of MATRIX and 'non-MATRIX' approved interventions (34.8%). Interestingly, almost half of the cases included within this study (47%) were not offered any interventions included in the MATRIX; yet, the vast majority of service users (90.4%) had at least one referring problem that would favour the partial use of the guideline. This may be related to the limited range of interventions available in the guidance for clinicians to choose based on the service users' needs.

A formulation-driven, rather than diagnostically-based, approach in the delivery of psychological services may also be one potential explanation to account for this discrepancy. Assessments may have led to a different understanding of the presenting problem, and therefore may have highlighted other directions for intervention. The diagnostic approach to mental health difficulties, that clinical guidelines are based-upon, is inconsistent with other leading documents in Clinical Psychology practice promoting formulation-guided approaches (e.g., BPS, 2011) and with cumulative evidence that indicate low adherence to guidance or policies that do not correspond to the level of complexity encountered in secondary and tertiary healthcare services (Bauer, 2002). Individuals with learning disabilities experience increased comorbidity, in comparison with populations without such disabilities (Deb, Thomas and Bright, 2001). In this study, 60.9% of cases had more than one referring problems, thus increasing the complexity for clinicians and potentially making the direct applicability of a single-diagnosis best practice guidance, such as

the MATRIX, more difficult. In such a service, an integrative, individualised approach may be more effective in meeting needs (Zarbo et al., 2016; Kinderman et al., 2008). However, little evidence exist regarding the efficacy of such an approach, given the overall challenges in evaluating complex interventions in health (Datta and Petticrew, 2013; Eells, 2013).

The findings regarding the use of the MATRIX amongst different disciplines within the service may be supporting the argument that Clinical Psychologists could be using a more integrative approach and an eclectic range of therapies, especially as complexity increases (Oliver et al., 2002). In particular, it was found that 57.1% of service users that worked with a Clinical Psychologist or trainee Clinical Psychologist were not offered any psychological therapy included in the MATRIX. However, only 17.6% of individuals who worked with Specialist Psychological Therapists (who have closely defined roles and are typically assigned cases that focus on their areas of expertise, i.e., low intensity CBT or behavioural interventions for challenging behaviour) were not offered MATRIX therapies.

It remains unclear whether this integrative approach is actually more beneficial to service users and effective in reducing symptoms, given that it is favoured in relation to treatments proposed in robust trials. The lack of standardised outcome measures for all cases reviewed within this NHS Board, during the time period that this study has focused on, limits the potential of answering this question directly. It is increasingly recognised, however, that this may be the optional approach, especially where engagement in therapy is challenging and when complexity increases (Evans and Gilbert, 2005; Stricker, 2010). This may be particularly true for the MATRIX

guideline, which lacks a range of treatment recommendations that clinicians could select based on service users' needs for the majority of the included problem areas, besides challenging behaviour.

In summary, this study suggests that in clinical practice, as with research (Oliver et al., 2002), the heterogeneity of people with learning disability may result in a need for increased flexibility in the delivery of psychological therapies. The potential reasons for this are outwith the scope of this study, but disparate cognitive and communication difficulties would be expected to place significant influences on this. The need for flexibility in clinical practice does not, of course, preclude the use of evidence-based interventions. It suggests, however, that the development and evaluation of standardised treatment packages may be more difficult in this population.

Further to this, the practice in services with poor adherence to guidelines is not necessarily opposed to their principles. For example, the MATRIX does highlight that those providing psychological therapies should deliver, plan and evaluate safe clinical practice when there is no adequate evidence base (NES, 2011), i.e., when complexity and comorbidity increases. It should also be noted that many of the psychological interventions identified in this study are routinely used within clinical practice and have a research evidence base, albeit that the quality of evidence was not considered sufficient to warrant inclusion in the learning disability section of the MATRIX, e.g., problem-solving or graded-exposure for anxiety. As such, in line with previous reports (Brown et al., 2011), the present results also highlight the urgent need for more research to further evidence such psychological interventions to use

with this population.

The challenges in conducting the present study perhaps also emphasise the complexity of this area. Neither referring problems nor psychological interventions were easy to place neatly into categories as they are rarely clearly defined and distinguishable (e.g., anger and challenging behaviour). This, of course, is essentially consistent with Clinical Psychology's role within mental health services (Lavender and Hope, 2007), which extends beyond the direct application of standardised treatment protocols for specific disorders. This does not suggest that best-practice guidance, such as the MATRIX, is not important or necessary to improve service delivery, but highlights that these may be of greater applicability for lower intensity problems or interventions in the context of a stepped-care/matched-care model, possibly even prior to cases reaching Clinical Psychology services.

Limitations

There are several limitations to be considered in the interpretation of the findings. The lack of effectiveness measures does not allow a discussion in relation to how current practice compares to the recommended interventions. The levels of the inter-rater agreement for the referring problems and interventions were moderate. Despite efforts to standardise this process by using a specially designed form, the identification of such data through letters and reports did require some level of judgement by the raters and, therefore, it involved a risk of increased bias in the reporting of the data. Future studies may consider the adoption of a prospective design, rather than retrospective, with the use of forms which would allow the therapists to describe their input, would resolve some of these issues. It would also

limit the possibility of input not having been captured due to limiting the case note review to reports and correspondence, rather than extensive examination of progress notes. Within this context, another limitation involves the inclusion of all case files, including ones that remain open to the service; thus, potentially missing some of the input eventually offered to these service users. Moreover, this study did not include other aspects of clinical practice within this service; e.g., sex offender treatments or social skills interventions for people with autism spectrum disorders. Finally, as no similar studies are available to compare the current findings with, it is not possible to exclude the possibility that these findings simply reflect the idiosyncrasies of the NHS health board in question, rather than being indicative of more systemic issues with the clinical governance document.

Conclusions

Despite these limitations, the current study provides a useful illustration of where current clinical practice fits in the context of national guidance, government priorities and emerging evidence-base in learning disabilities. It is possible that a review of the service planning and development may focus on increasing adherence to national guidance. The findings, on the other hand, may also open a discussion regarding the pragmatic implications and challenges involved in the application of such guidelines in specialist services, especially in areas where limited research exists. There remains the risk that applying rigid therapeutic recommendations may limit opportunities for integrative practice.

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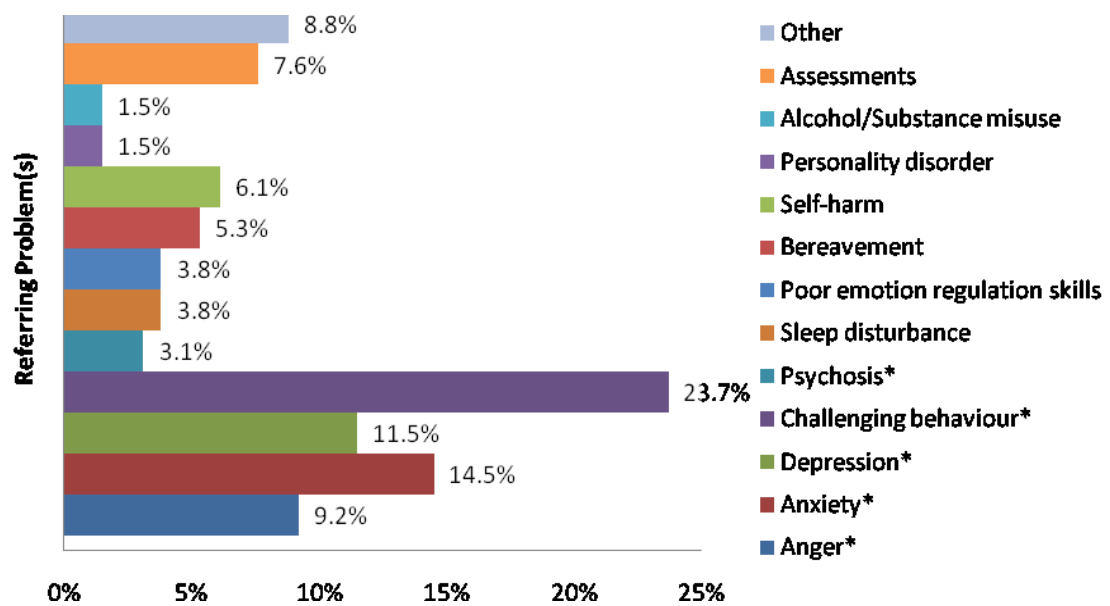
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**Referring problems included in the MATRIX.*

Figure 1. Percentages of referring problems across cases

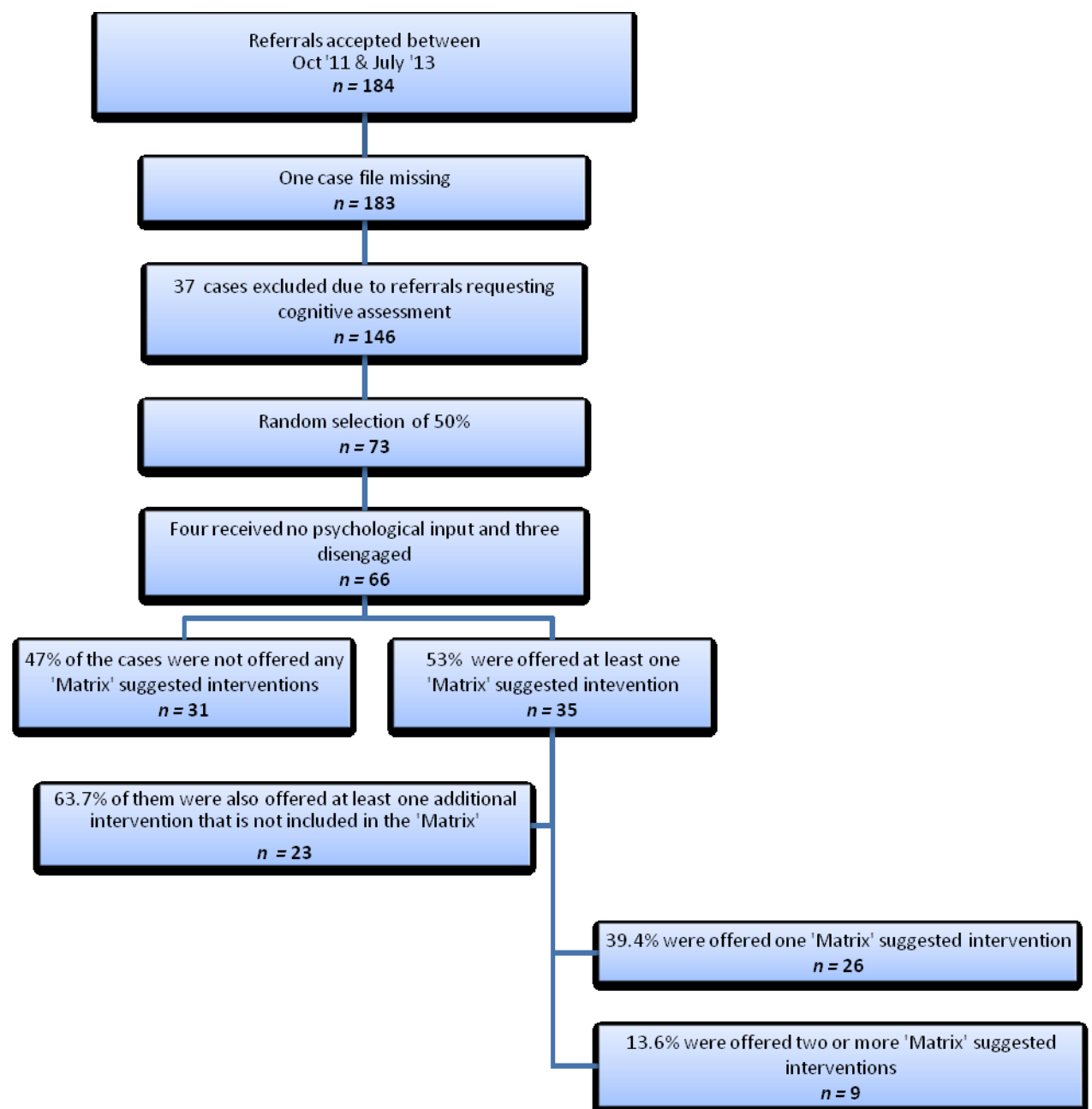


Figure 2. Flowchart of case files reviewed

Table 1. Frequencies of psychological therapies across case files

Psychological Therapies	Frequency	Percentage (%)
Indirect systemic work and staff training	24	14
Behavioural activation treatment	22	12.8
Cognitive-behavioural Therapy (CBT)	21	12.2
Psycho-education	19	11
Applied behaviour analysis	17	9.9
Positive behaviour support	17	9.9
Fostering the development of emotional regulation/ coping skills (e.g., distraction, talking to someone)	11	6.4
Progressive muscle or imaginal relaxation	9	5.2
Problem-solving	8	4.7
Diaphragmatic breathing retraining	4	2.3
Person-centred counselling	3	1.7
Graded exposure and systematic desensitisation	3	1.7
Social skills training	3	1.7
Undefined or unspecified intervention	3	1.7
Anxiety management group (CBT-based)	2	1.2
Social stories	2	1.2
Management of neuropsychological impairments	2	1.2
Behavioural family therapy	1	0.6
Narrative therapy	1	0.6